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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/531,438	03/20/2000	Maryse Gibert	0660-0172-0 CONT	5905

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ALEXANDRIA, VA 22314

EXAMINER

PORTNER, VIRGINIA ALLEN

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 11/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/531,438

Applicant(s)

GIBERT ET AL.

Examiner

Ginny Portner

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 August 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 42-73, 80-91, 94 and 95 is/are pending in the application.
- 4a) Of the above claim(s) 90 and 91 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 42-59 and 61-73 is/are allowed.
- 6) ☒ Claim(s) 60, 81, 83, 85, 87, 89, 91 and 95 is/are rejected.
- 7) ☒ Claim(s) 80-89 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1645

DETAILED ACTION

Claims 42-73,80-91, and 94-95 are pending.

Claims 42-73, 80-89 and 94-95 are under consideration

Claims 90-91 stand withdrawn from consideration.

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Objections/Rejections Withdrawn

2. Claims 60, 81,83,85,87 and 89 rejected under 35 U.S.C. 112, first paragraph (scope) is herein withdrawn in light of the amendment of the claims to recite specific hybridization conditions.

3. The rejection of claims 42(b) and claims 50-51,54-55(b) under 35 U.S.C. 102(b) as being anticipated by Graves et al (1986) has been obviated in light of the amendment of the claims to require the purified nucleic acid to hybridize over the full length of SE QID NO 3 and to evidence transcriptional promoter activity.

4. Claims 60, and 80-89 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention in light of the amendment of the claims to recite specific hybridization conditions.

5. The term "stringent conditions" in all of the claims (claims 42-73, 80-89) is a relative term which renders the claim indefinite; this rejection has been obviated through amendment of the independent claims to recite the phrase ----- 42 degrees C, 50% formamide, 5X SSC and 1X Denhardt -----(support found on page 5, paragraph 2, lines 6-7).

6. Claim 42-59,61-73 rejected under 35 USC 112, second paragraph have been amended to no longer recite the phrase: " hybridizing the all of the complementary strand" ; this rejection has been obviated.

Objections/Rejections Maintained

7. Claims 60, 81, 83, 85,87, 89, and new 95 are rejected under 35 U.S.C. 102(b) as being anticipated by Brown et al, for reasons of record and responses set forth below.

8. Claims 60,81,83,85,87, 89 and new claim 95 are rejected under 35 U.S.C. 102(b) as being anticipated by Hunter et al, for reasons of record, and responses set forth below.

Response to Arguments

9. The rejection of claims 60, 81, 83, 85, 87, 89, 95 under 35 U.S.C. 102(b) as being anticipated by Brown et al, is traversed on the grounds "Brown is relied upon to describe some portion of a sequence of a secretory leader".

10. It is the position of the examiner that Applicant's statement is true and agrees that Brown still anticipates the instantly claimed invention because what is now claimed in claim 60(b), includes fragments of is a sequence that will hybridize to a portion of SEQ ID No 4, encodes a secretion signal peptide, and is a sequence obtained from a Clostridium strain. Brown discloses a secretion signal peptide that meets all of these claim limitations. (see Figure 51, clostripain leader, defined to be the secretion leader sequence of Dargatz et al (1993) deposited in EMBL (Feb 1992) accession number X63673 and under Swiss-Prot accession number P09870, the first 27 amino acids which is linked as a fusion protein to at least 3 additional amino acids and therefore is a peptide that comprises at least 30 amino acids). The rejection is maintained for reasons of record.

11. The rejection of claims 60, 81, 83, 85, 87, 89 and 95 under 35 U.S.C. 102(b) as being anticipated by Hunter et al, is traversed on the grounds that the disclosed sequence of Hunter et al: by asserting Hunter et al does not describe comprises a hydrophobic region bordered by charged amino acids, wherein the "aspartic acid is not part of the signal sequence".

12. It is the position of the examiner that the phrase "bordered by charged amino acids" does not require the charged amino acid to be a part of the secretion signal peptide, but to be on the border, the term "border" including the meaning of "being adjacent to another or share a boundary" of the secretion signal peptide. Based upon this reading of the term "bordered", Hunter et al still anticipates the instantly claimed invention as now claimed.

New Grounds of Objection

Claim Objections

13. Amended Claims 81, 83, 85, 87, 89 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim.

Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claims 81, 83, 85, 87 and 89 depend from claim 60 which requires the secretion signal peptide to comprise a hydrophobic region bordered by charged amino acids, but claims 81, 83, 85, 87 and 89 are claimed in such a way that the secretion signal peptide no longer is required to comprise the hydrophobic region bordered by charged amino acids and are therefore broader in scope than the independent claims from which they depend. The combination of claim limitations recited in claims 81, 83, 85, 87, 89 is not the combination of claim limitations set forth in paragraph (b) of claim 60.

Allowable Subject Matter

14. Claims 42-59, 61-73 define over the prior art of record and therefore define allowable subject matter.

15. Claims 80, 82, 84, 86, 88 and 94 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

16. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

1. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginny Portner whose telephone number is (571) 272-0862. The examiner can normally be reached on M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Vgp
October 28, 2005


LYNETTE R. F. SMITH
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER

Biow
Figure insert into
office action

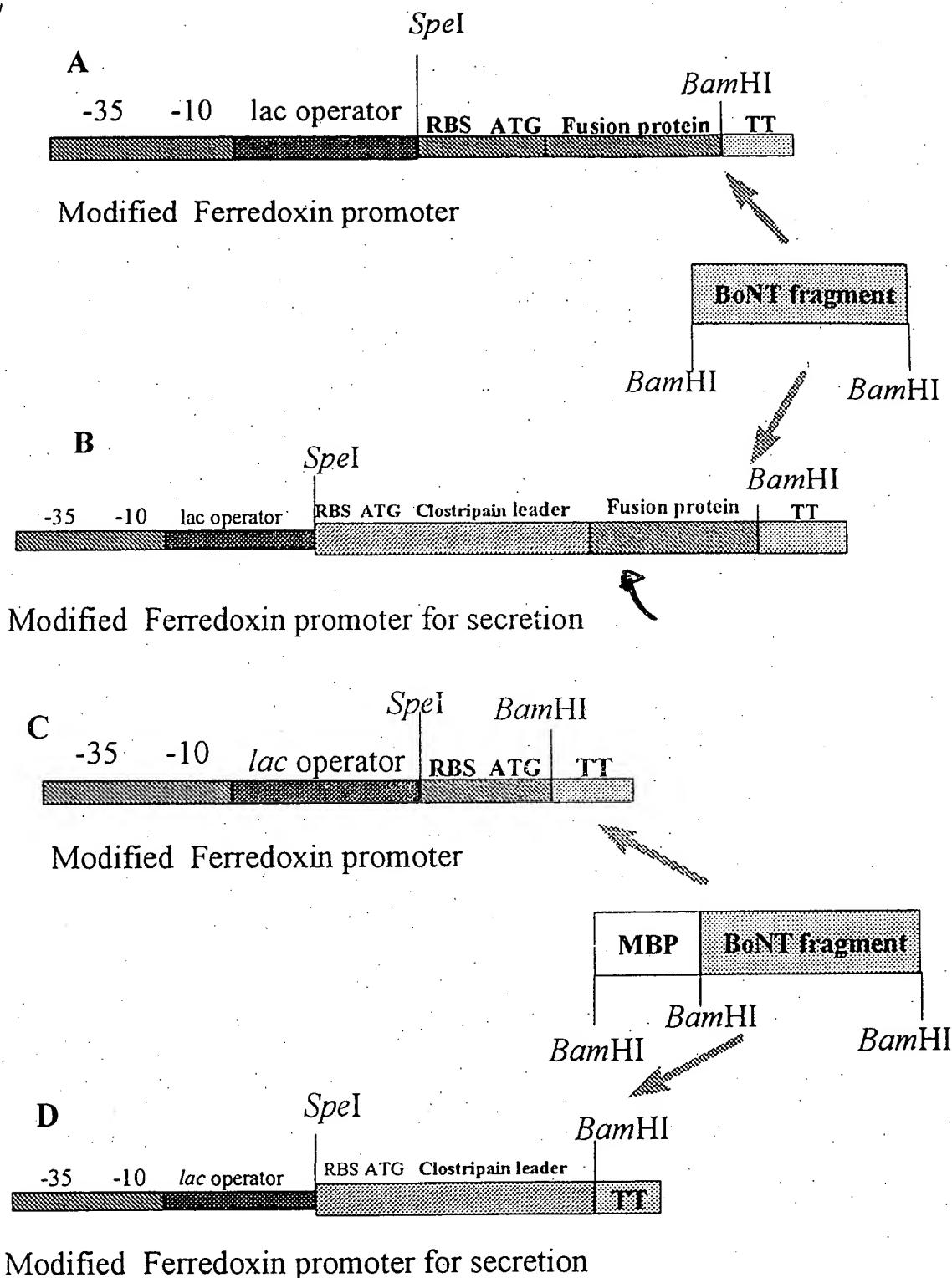


Figure 51. Diagram depicting strategy for BoNT/A expression. The modified *fer* promoters of the two types of integration vector are represented; **A & C.** pIntCmFdOpTT lacks the clostripain leader and was designed for production of non-secreted recombinant protein. **B & D.** pIntCloop possesses the clostripain leader and was designed to export the recombinant BoNT/A fusion protein into the extracellular culture fluid. **A & B.** have the GST or polyHis ligated prior to the insertion of BoNT/A fragments. **C & D.** requires the simultaneous insertion of the MBP:BoNT/A, by virtue of the extra *Bam*HI restriction site.